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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,571	02/24/1998	CHARLES R. CANTOR	25491-2401G	7542
20985	7590	02/16/2006	EXAMINER	
FISH & RICHARDSON, PC			FORMAN, BETTY J	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	
			1634	
DATE MAILED: 02/16/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/030,571

Applicant(s)

CANTOR ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 74-76, 92-94, 123, 124, 127-133 and 135-139 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 74-76, 92-94, 123, 124 and 136 is/are allowed.
- 6) ☒ Claim(s) 127-133, 135 and 137-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 November 2005 has been entered.

#### ***Status of the Claims***

2. This action is in response to papers filed 16 November 2005 in which claims 74, 127 and 135 were amended and claims 70, 72-73 and 77-79 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 July 2005, not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments and new grounds for rejection. New grounds for rejection are discussed.

Claims 74-76, 92-94, 123-124, 127-133 and 135-139 are under prosecution.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 127-133, 135, 137-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent Claim 127 (from which the remaining claims depend) has been amended to define the selected base as being one of "adenosine-5'-phosphate, deoxyadenosine-5'-phosphate, deoxythymidine-5'-phosphate, uridine-5'-phosphate, guanine-5'-phosphate, deoxyguanosine-5'-phosphate, cytidine-5'-phosphate or deoxycytidine-5'-phosphate".

Applicant points to pages 10 and 12 to support the added limitation. Page 10 defines the bases present in DNA and RNA. Page 12 defines the probe subsets as follows:

The probes are divided into four subsets. In each, one of the four bases is used at a defined number of positions and all other bases except that one on the remaining positions. Probes from the first subset contain two elements, A and non-A (A = adenosine).

The passage does not define or limit "non-A". The passage does not define or limit the four bases to those previously described (e.g. those cited on page 10). Applicant appears to be amending the claims to overcome the probe sets comprising ddNTP in the cited reference. The instant specification provides no teaching of the newly claimed probe sets. In contrast to a supportive teaching, the specification (on page 13), which immediately follows the cited passage, specifically teaches use of ddNTP. Therefore, the specification does not provide any disclosure to support the newly claimed probe sets.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED.

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*APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 127-133, 135, 137-139 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes et al (WO 90/06045, published 14 June 1990).

Regarding Claim 127, Holmes et al discloses an array of probes wherein each probe comprises a single-stranded portion comprising a variable region (non-hybridized target) and a double-stranded portion (oligo-dT) wherein the probes are divide into four subsets wherein each subset a nucleic acid base occupies a defined number of positions (e.g. biotinylated nucleotide at the end, page 8, lines 7-11 or incorporated ddNTP, page 14, lines 1-15) and all other bases (non-biotinylated A, T, C, G) occupy the remaining positions (page 15, lines 15-35).

The above interpretation of Holmes describes the double stranded portion of the probes following primer extension and NTP incorporation to complement a portion of the single stranded portion.

Prior to primer extension, the single stranded portion of the probes has the complement i.e. the single stranded portion of each set has a base at a defined number of positions and all other bases occupy the remaining positions as evidenced by the extension product and the selected base is one of those claimed. Therefore, the hybridized and unextended probes of Holmes are encompassed by the claims as amended.

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Regarding Claims 138 and 128, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7- 11 and page 11, lines 23-26).

Regarding Claim 129, Holmes et al disclose the array wherein the probes are labeled (page 15, lines 15-35).

Regarding Claim 130, Holmes et al disclose the array wherein the label is a radioisotope or florescent molecule (page 13, line22-page 14, line 29).

Regarding Claim 131, Holmes et al disclose the array wherein the nucleic acids are DNA or RNA (page 2, lines 9-22).

Regarding Claim 132, Holmes et al disclose the array wherein the solids support is metal (page 4, lines 14-35).

Regarding Claim 133, Holmes et al disclose the array wherein the solid support is three-dimensional having multiple binding sites (page 5, line 19-page 7, line 9).

Regarding Claim 135, Holmes et al disclose the array wherein the probes comprise a base analog (i.e. biotinylated nucleotide at the end, page 8, lines 7- 11).

Regarding Claim 136, Holmes et al disclose the array wherein the double stranded portion includes a restriction site (page 18, lines 32-37).

Regarding Claims 137, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7-11 and page 11, lines 23-26).

Regarding Claims 138, Holmes et al disclose the array wherein the probes are fixed to a solid support via a coupling agent e.g. biotin (page 8, lines 7- 11 and page 11, lines 23-26).

Regarding Claims 139, Holmes et al disclose the array wherein the probes are fixed to a solid support (page 8, lines 7- 11 and page 11, lines 23-26).

#### **Response to Argument**

7. Applicant argues that Holmes teaches the probes wherein the selected base is the incorporated ddNTP. Applicant asserts that the claims, as amended, define the selected base

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over the ddNTP of Holmes. The argument has been considered but is not found persuasive because, as stated above, the probes, prior to ddNTP incorporation contain a single stranded portion having the complement to the subsequently extended portion. This complement does not contain the ddNTP, but the complement to the ddNTP. Therefore, the hybridized probes of Holmes are encompassed by the claimed probes. It is noted that the claims do not define the selected nucleotide base as being part of the single stranded or double stranded portion. For this additional reason, the probes of Holmes are encompassed by the claimed probes.

### **Conclusion**

8. Claims 74-76, 92-94, 123-124 and 135 are free of the prior art and may be placed in condition for allowance following resolution of the above rejections.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

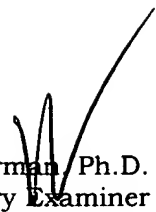
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
February 13, 2006